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APPLICATION NUMBER: *60/507,282*
FILING DATE: *September 30, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/31886*

Certified by

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CERTIFICATE OF EXPRESS MAIL

I hereby certify that this paper and the documents and/or fees referred to as attached therein are being deposited with the United States Postal Service on September 30, 2003 in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10, Mailing Label Number ER418305352, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Tony D. Alexander

PROVISIONAL PATENT APPLICATION TRANSMITTAL 37 C.F.R. §1.51(c)(1) & 37 C.F.R. §1.53(c)

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Sir: This is a request for filing a patent application under 37 C.F.R. §1.51(c)(1) & 37 C.F.R. §1.53(c) in the name of inventors: Thomas Nißl & Eric K. Mangiardi.

For: **REMOVABLE STENT**

Application Elements:

☒ 13 Pages of Specification, Claims and Abstract
☒ 05 Sheets of Drawings

Accompanying Application Parts:

☒ Return Receipt Postcard
☒ Applicant Claims Small Entity Status Pursuant to 37 C.F.R. 1.27
☒ The Commissioner is authorized to charge the $80.00 filing fee, any fees beyond the amount enclosed that may be required, or to credit any overpayment, to Deposit Account No. 50-2764 (Order No. _____).

General Authorization for Petition for Extension of Time (37 C.F.R. §1.136)

☒ Applicants hereby make and generally authorize any Petitions for Extensions of Time as may be needed for any subsequent filings. The Commissioner is also authorized to charge any extension fees under 37 C.F.R. §1.17 as may be needed, to Deposit Account No. 50-2764 (Order No. _____).

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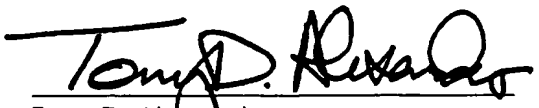
Date: September 30, 2003



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REMOVABLE STENT

FIELD OF INVENTION

The invention is relative to a stent with a tubular support frame of axially successive, interconnected annular segments.

BACKGROUND OF THE INVENTION

Stents are used in the treatment of stenoses. Stenoses are closures and constrictions of tubular body canals such as, e.g., air passages, bronchia, the esophagus, bile ducts, urinary passages, aorta and other body canals that are acquired congenitally or conditioned by disease. Tumors that press on the body canals or deposits that close the body canals are frequently a cause of stenoses. Stenoses can be opened by operative and non-operative measures. In the case of non-operative measures, stents are introduced by catheter techniques or introducing aids into the intracorporal vessel in the area of the stenosis. Stents function there as a vascular prosthesis for supporting the inner vascular walls.

Stents exist is various embodiments and designs of the support frame. Frequently used stents comprise a tubular metallic support frame consisting of several annular segments. These segments are usually formed from struts that endlessly follow each other in a corrugated or meandering fashion via arced sections. Annular segments that are adjacent in the longitudinal direction of the stents are firmly connected via connector struts. Such a stent is known from EP-B 0,364,787.

Many stents have fixed final diameters and are self-expanding. Other embodiments can be altered in diameter by suitable tools, e.g.,

balloons or spreaders in order to adapt them to the anatomical situation. Furthermore, stents consisting of a so-called memory form alloy with memory effect also belong to the state of the art. The most frequently used memory form alloy is nitinol, that is a nickel-titanium alloy. A stent manufactured from it transits from its compressed initial state into its widened-out support state as a function of the temperature.

A stent within the scope of DE 100, 26, 307 A1 belongs to the state of the art and comprises a support frame on whose ends several holding elements are formed distributed in the circumferential direction. The stent can be coupled via the holding elements to a positioning element of the introducing catheter.

The stent known from DE 199 50 756 A1 comprises an articulated construction in its non-expanded state consisting of several annular segments that intermesh in the longitudinal direction and thus can pivot against each other without a fixed physical connection existing between them. In the widened-out state the couplings between the individual annular segments are released and separated in order to completely separate the annular segments from each other in the final widened-out state.

However, stenoses seldom have a uniform course by nature. They vary in their local diffusion [extent], e.g., in their length and as regards the constriction force. It turned out in practice that the support frames of stents frequently either do not make the necessary radial forces available for sufficiently resisting a stenosis even over a rather long time period or are configured in such a manner that they hinder the functioning of the vessel. It is therefore desirable to have a flexibly adaptable stent available.

The invention has the problem, starting from the state of the art, of making a stent available that can be flexibly shaped and that can be adapted as regards its geometry, in particular in its length and/or its support properties in an advantageous manner to the particular anatomic conditions.

SUMMARY OF EXEMPLARY EMBODIMENTS

The invention solves this problem in a stent in accordance with the features of protective Claim 1 in which the support frame is formed by several axially successive annular segments and in which at least two adjacent annular segments can be connected by positively intermeshing coupling elements.

The stent in accordance with the invention and the annular segments used to build the stent are constructed in a modular [building-block] system and can be individually composed. The stent can be used wherever different lengths and/or different properties, e.g., different degrees of radial forces or different geometries should be used or must be used.

A stent can be constructed or composed of individual annular segments or of annular segments combined in groups adapted to the particular requirements of use of the stenosis to be treated. A rapid reaction time for specific and specially adapted stents for a patient is possible.

The stent of the invention is adapted functionally by means of the combination of annular segments with different properties, in particular with radial forces that differ from each other. This can take place by the combination of annular segments with a differing design and/or consisting of different materials.

The suggested stent also has manufacturing and economical advantages. Thus, the rejection rate can be reduced by using short, individual annular segments. An individual annular segment is, e.g., 20 mm long. A complete stent can then be composed of 6 individual annular segments with a total length of 120 mm. If an annular segment is defective, only this single short annular segment needs to be replaced, whereas, in the case of a support frame with a one-piece construction the entire stent would be unusable.

The connection of the annular segments via the coupling elements is positive, but articulated in a limited manner. This measure is advantageous for the direction of the curves [curve rise?] of the stent.

The annular segments are connected via positively intermeshing coupling elements. The coupling elements are preferably designed as complementary claw connectors, as provided in protective Claim 2. It is advantageous if both coupling elements project axially relative to the annular segments in the direction of the longitudinal axis of the stent (protective Claim 3). However, it is also conceivable that one of the coupling elements is designed inside the annular segment so that only one corresponding coupling element projects in the axial direction of the stent. It can be advantageous in practice to use special terminal annular segments on the free ends of a stent of the invention which segments comprise coupling elements only on one side in the direction of the middle of the stent.

The annular segments are positively connected by the coupling elements. To this end the coupling elements have undercut areas for producing a stable connection. The undercut areas can be curved (protective Claim 4). Straight-line undercut areas are also advantageous (protective Claim 5). In addition, a combination of

curved undercut areas and of straight-line undercut areas on the coupling elements is also possible. The coupling elements are supported on each other by the undercut areas so that a reliable, positive coupling of the annular segments among themselves is assured.

A number of annular segments can be advantageously interlocked to stent sections by connector struts, as provided in protective Claim 6. According to this claim a number of annular segments are firmly connected by connector struts. The individual sections again comprise coupling elements that make possible a positive connection of the annular segments or of the stent sections to each other in accordance with the invention.

According to the features of protective Claim 7 the annular segments are formed by corrugated struts that endlessly follow each other. All deformable, medically possible metals or metal alloys can be used in this instance, e.g., high-grade steel, cobalt alloys, technical pure iron or nickel-titanium alloys or other medical implant materials.

The invention is described in detail in the following using exemplary embodiments. Further objectives, features and advantages of the invention will be apparent from the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 shows the stent pattern of a stent in accordance with the invention in a developed view.

Figure 2 shows a section of the stent pattern according to figure 1.

Figure 3 shows the coupling elements of the stent according to figures 1 and 2 on an enlarged scale.

Figure 4 shows a section from the stent pattern of another embodiment of a stent.

Figure 5 shows the coupling elements of the stent according to figure 4 on an enlarged scale.

Figure 6 shows a section from the stent pattern of another embodiment of a stent.

Figure 7 shows the coupling elements of the stent according to figure 6, also on an enlarged scale.

DETAILED DESCRIPTION OF AN EMBODIMENT

Figure 1 shows a stent 1 manufactured from metal in the developed view [unwound state] of its support frame 2. In practice, support frame 2 is designed to be tubular. It consists of several successive annular segments 3 - 16. Annular segments 3 - 16 have a corrugated configuration consisting of struts 18, 19 endlessly following each other via arced sections 17.

Adjacent annular segments 6, 7 and 7, 12 and 13 are connected by positively intermeshing coupling elements 20, 21. It can also be recognized that annular segments 3 – 7, 7 - 12 and 13 - 16 are interlocked by connector struts 22 to stent sections 23, 24, and 25. Connector struts 22 are configured in a V-shaped strut section 26 arranged in the space between two annular segments 3 – 6, 7 - 12 and 13 - 16 that are adjacent with axial spacing.

The embodiments of the stents, sections of which are shown in figures 4 to 7, correspond in their basic construction to a stent 1 as is described using figure 1. The stents differ in the configuration of their

coupling elements, by means of which a detachable, positive connection is established between annular segments 6, 7 and 12, 13.

Coupling elements 21, 22 and 27, 28 and 29, 30 are designed as complementary claw connectors 31, 32 and 33, 34 and 35, 36. They mutually supplement each other in such a manner that a positive connection is produced between annular segments 6, 7 and 12, 13 and therewith between stent sections 23, 24, 25 by the mutual engagement.

Coupling elements 20, 21 in the embodiment according to figures 1 to 3 are designed as hook-shaped claw connectors 31, 32 with undercut areas 37 running in a straight line and undercut areas 38 that are curved. Claw connector 31 and claw connector 32 both have a finger-shaped hook section 39 that forms a type of mouth in which prong-shaped abutment section 40 of the other claw connector 31 or 32 engages.

Recess 42 can also be recognized in connection area 41 of coupling elements 20. This recess supports the flexibility of annular segments 6 and 13 in connection area 41 and contributes to the saving of material and of weight.

Moreover, it can be recognized that coupling elements 21 are connected between two struts 18, 19 via longitudinal section 43 running parallel to longitudinal axis L of the stent at the lowest point on arced section 17.

Coupling elements 27, 28 are, as described for figures 4, 5, also designed as complementary claw connectors 33, 34 and claw connector 33 on the left in the plane of the figure is configured in a fork shape. The right claw connector 34 engages into fork 44 with its roundly configured abutment head 45. Undercut areas 46, 47 formed on claw connectors 33, 34 run in a uniformly curved manner.

Circular recess 48 is provided in abutment head 45. Recess 48 contributes to the saving of weight but can also be used to receive a marker serving to improve the identification of the stent during the implantation process or subsequently to it.

Figures 6,7 show another alternative embodiment of coupling elements 29, 30 via which a detachable, positive connection can be established between two adjacent annular segments 6,7 and 12, 13 of stent 1.

Even coupling elements 29, 30 comprise two complementary claw connectors 35, 36 with a trapezoidal configuration. Claw connector 35 comprises two finger prongs 49, 50 with straight undercut areas 51, 52 that form mouth-like recess 53 for trapezoidally formed prong 54 of claw connector 36. Prong 54 engages into recess 53, where it is supported with its straight undercut areas 55, 56. Furthermore, prong 54 has a widened-out base section 57 that merges into longitudinal section 58 for connecting to arced section 17 between two struts 18, 19.

List of reference numerals

1 – stent
2 - support frame
3 - annular segment
4 - annular segment
5 - annular segment
6 - annular segment
7 - annular segment
8 - annular segment
9 - annular segment
10 - annular segment

11 - annular segment

12 - annular segment

13 - annular segment

14 - annular segment

15 - annular segment

16 - annular segment

17 – arced section

18 – strut

19 – strut

20 - coupling element

21 - coupling element

22 – connector strut

23 - stent section

24 - stent section

25 – stent section

26 - strut section

27 - coupling element

28 - coupling element

29 - coupling element

30 - coupling element

31 - claw connector

32 - claw connector

33 - claw connector

34 - claw connector

35 - claw connector

36 - claw connector

37 - straight undercut area

38 - curved undercut area

39 - hooked section

40 - abutment section
41 - connection area
42 – recess
43 - longitudinal section
44 – fork
45 - abutment head
46 - undercut area
47 - undercut area
48 – recess
49 - finger prong
50 - finger prong
51 - undercut area
52 - undercut area
53 – recess
54 – prong
55 - undercut area
56 - undercut area
57 - base section
58 - longitudinal section
L - longitudinal axis of stent

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes, which come within the meaning and range of equivalency of the claims, are to be embraced within their scope.

CLAIMS

What is claimed is:

1. A stent with a tubular support frame (2) of axially successive, interconnected annular segments (3 – 16), characterized in that at least two adjacent annular segments (6, 7 and 12,13) are be connected by positively intermeshing coupling elements (20, 21; 27, 28; 29, 30).

2. The stent according to Claim 1, characterized in that the coupling elements (20, 21, 27, 28, 29, 30) are designed as complementary claw connectors (31, 32, 33, 34, 35, 36).

3. The stent according to Claim 1 or 2 characterized in that the coupling elements (20, 21, 27, 28, 29, 30) project axially relative to the annular segments (6,7, 12, 13) in the direction of the longitudinal axis (L) of the stent.

4. The stent according to one of Claims 1 to 3, characterized in that the coupling elements (20, 21, 27, 28) comprise curved undercut areas (38, 46, 47).

5. The stent according to one of Claims 1 to 3, characterized in that the coupling elements (20, 21, 29, 30) comprise undercut areas (37, 51, 52, 55, 56) running in a straight line.

6. The stent according to one of Claims 1 to 5, characterized in that annular segments (3–6, 7–12, 13–16) are interlocked by connector struts (22) to stent sections (23, 24, 25).

7. The stent according to one of Claims 1 to 6, characterized in that the annular segments (3–6) are formed by struts (18, 19) that endlessly follow each other in a corrugated manner.

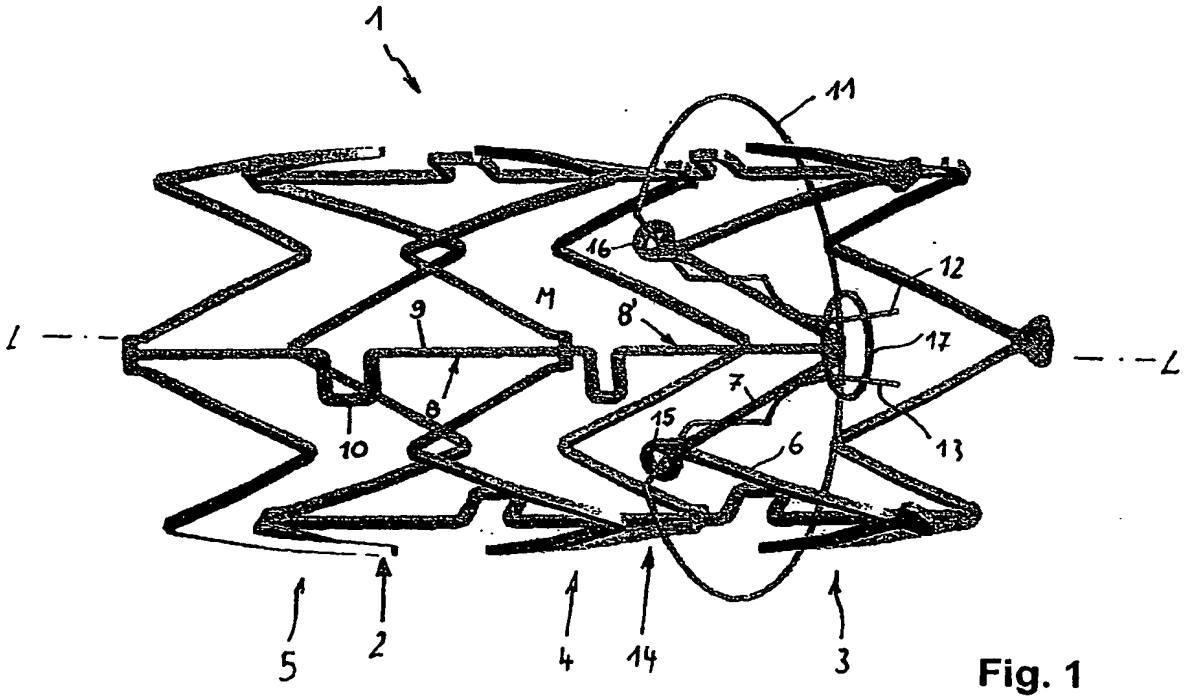

Fig. 1

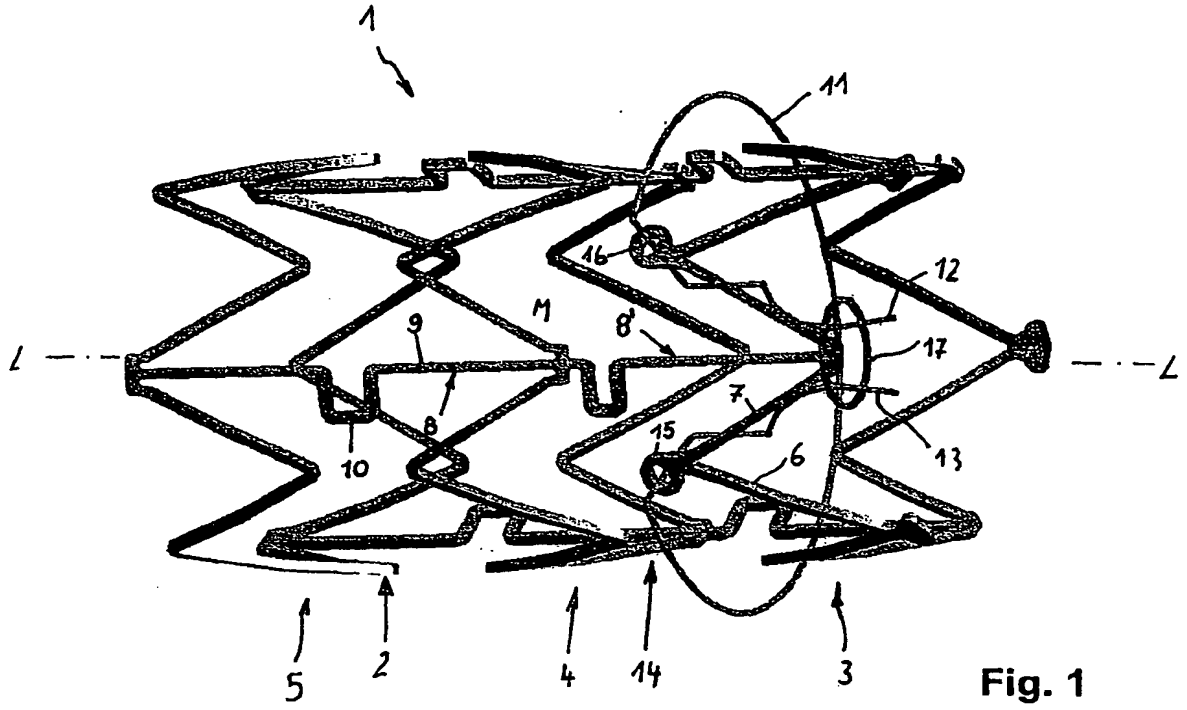
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Fig. 1

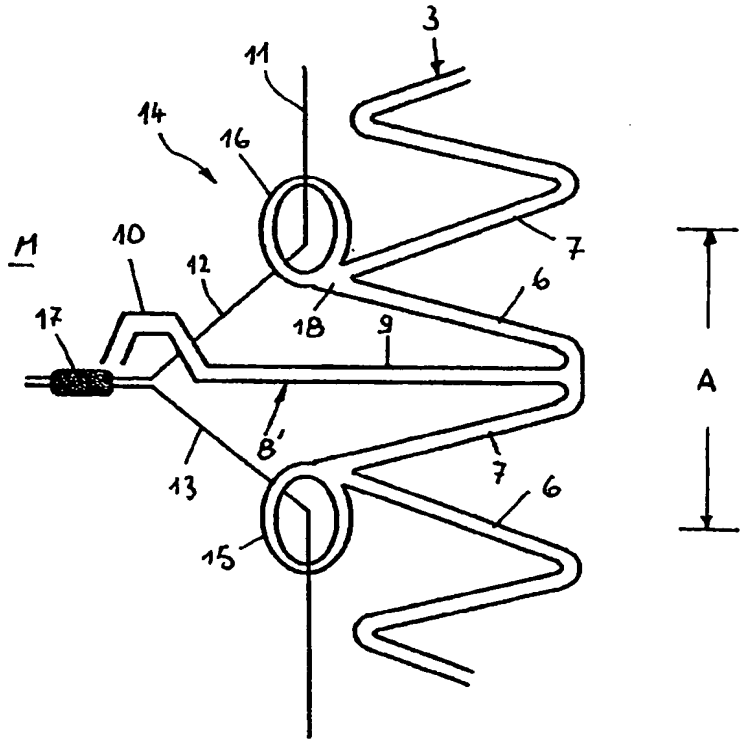
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Fig. 2

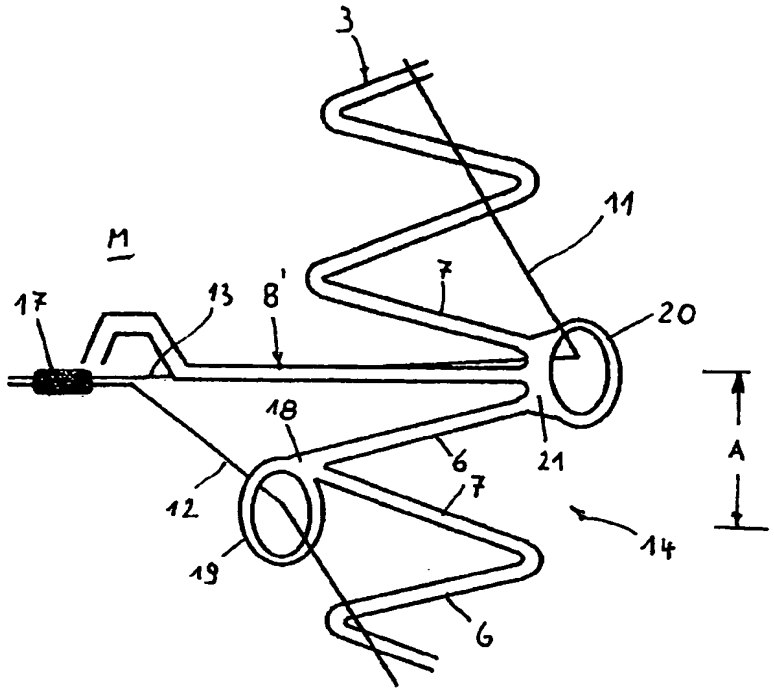
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Fig. 3

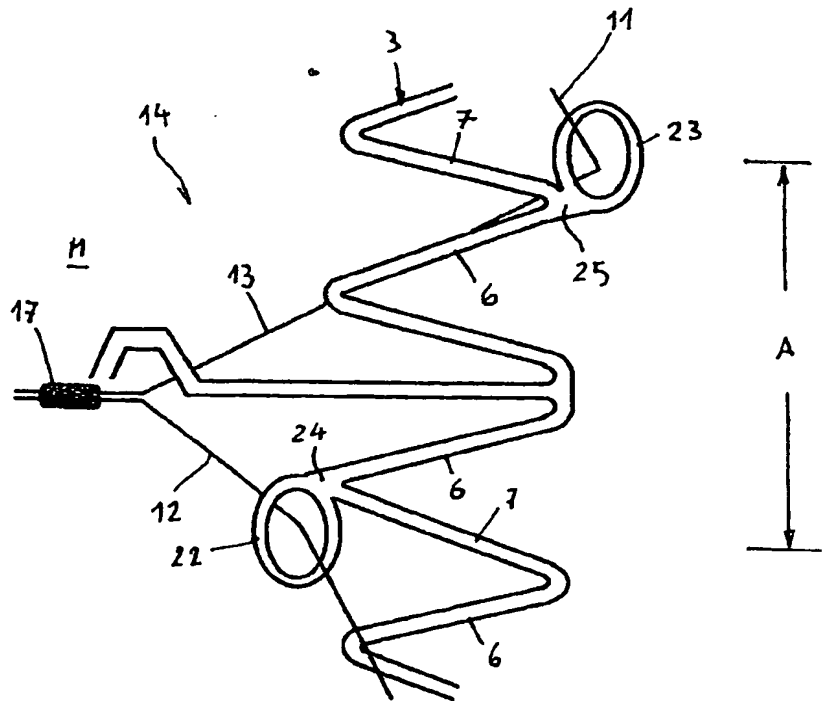
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Fig. 4

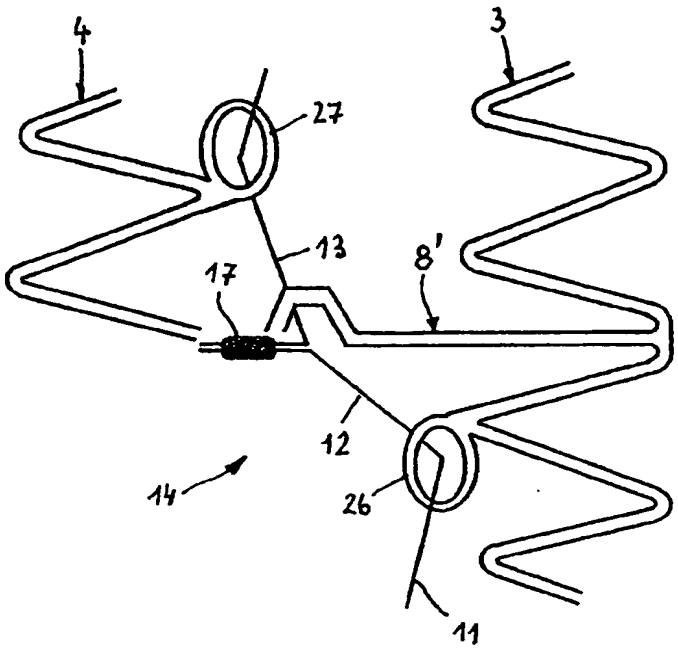

Fig. 5

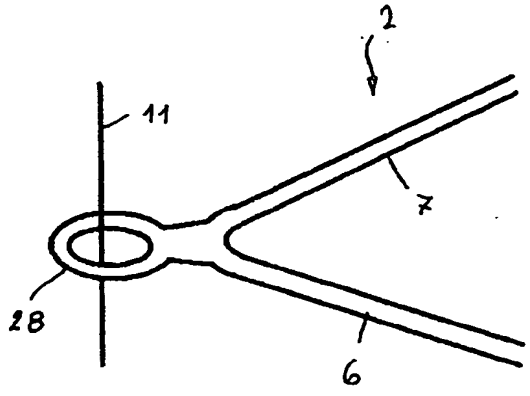

Fig. 6

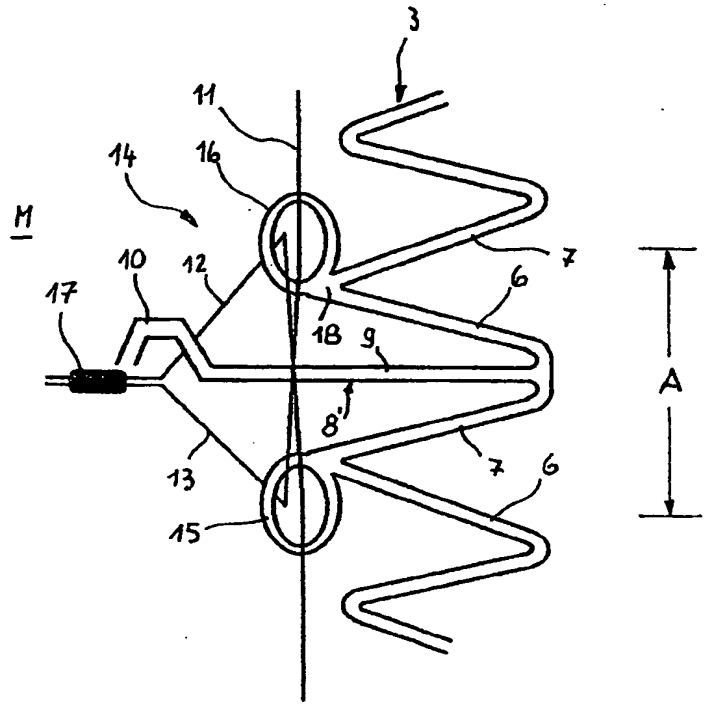

Fig. 7

REMOVABLE STENT

ABSTRACT OF THE DISCLOSURE

The invention relates to a stent with a tubular support frame consisting of axially sucessively following, interconnected annular segments, the support frame is surrounded on its outside by suture. The suture ends are guided via a deflection from the outside into the support frame, where they are coupled by a connnector that may be radiopaque. Deflection is realized bby tow deflection elements in the form of eyelets profided on one of the annular segments. Deflection elements are arranged on the circumference of the support frame at an invterval from one another and may be provided on the inside of the annular segments.

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/031886

International filing date: 29 September 2004 (29.09.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/507,282
Filing date: 30 September 2003 (30.09.2003)

Date of receipt at the International Bureau: 01 November 2004 (01.11.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

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